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| APPLICATION NO. | FILED DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|------------|----------------------|---------------------|------------------|
| 09/843,132 | 04/25/2001 | John P. McKearn | 3167/12 | 8349 |

7590 10/04/2002

Pharmacia Corporation
Corporate Patent Department
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[REDACTED] EXAMINER

GOLDBERG, JEROME D

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1614

DATE MAILED: 10/04/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/843,132 | MCKEARN ET AL. |
| | Examiner | Art Unit |
| | Jerome D Goldberg | 1614 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM

THE MAILING DATE OF THIS COMMUNICATION.

Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.

- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-181 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) Claim(s) ____ is/are allowed.
- 6) Claim(s) ____ is/are rejected.
- 7) Claim(s) ____ is/are objected to.
- 8) Claim(s) 1-181 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on ____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.

- 4) Interview Summary (PTO-413) Paper No(s) ____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____

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Restriction to one the following invention is required under 35 U.S.C. 121.

Group I: Claims 1-139 drawn to composition and method for treating neoplasms in a host employing an enhanced combination of a DNA topoisomerase I inhibitor and a cyclooxygenase – 2 inhibitor (COX-2 inhibitor).

Group II: Claims 140-181 drawn to method for treating DNA topoisomerase I inhibiting agent – related diarrhea in a host by administering a COX-2 inhibitor. With regard to the enhanced combination, see page 19, lines 1-12 of the specification.

Applicants state on lines 8-12 that "further use and advantage is that the present inventive combination will allow therapeutically effective individual dose levels of the DNA topoisomerase I inhibitor and the selective cyclooxygenase – 2 inhibitor which are lower than the dose levels of each inhibitor when administered to the patient as a monotherapy". Therefore, Applicants if elect either Group I or Group II, is require to elected a single enhanced combination of one DNA topoisomerase I inhibitor with one COX-2 inhibitor.

The several inventions above are independent and distinct, each from the other, as they have acquired a separate status in the art as a separate subject matter for inventive effect and require independent searches. It is noted that a reference to one enhanced combination of drugs would not be a reference to another enhanced combination of drugs under 35 U.S.C. 103. Further, the claims read on a multitude of enhanced combinations of drugs, which would require many field of searches that would be an undue burden on the Examiner. Therefore, restriction for examination purposes is proper.

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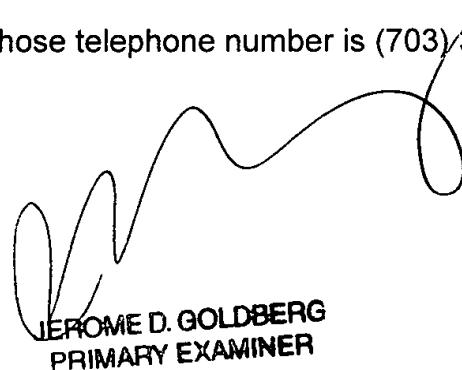
Applicants are required to make a provisional election even though this requirement is traversed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerome Goldberg whose telephone number is (703) 308-4606. The examiner can normally be reached on Monday to Thursday from 9:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Goldberg/LR
September 26, 2002



JEROME D. GOLDBERG
PRIMARY EXAMINER